K021622

Section I 510(k) Summary of Safety and Effectiveness

Applicant:

APR 0 1 2003

Hill-Rom Air Shields
330 Jacksonville Road
Hatboro, Pa 19040

Registration No: 2510954

Contact Person:

Monica Ferrante
Phone 215-682-8691
Fax 215-681-8689

Device trade/proprietary name:

Minolta Hill-Rom Air Shields JM 103

Device common/usual/classification name:

Jaundice Meter

Classification:

Clinical Chemistry Test Systems
21 CFR 862.1113
Bilirubin in the Neonatal Test System, MQM, Class I

Performance Standards:

None applicable

Predicate Device:

JM 102 Jaundice Meter K972309

Device Description:

The JM 103 Jaundice Meter is designed to provide a non-invasive measurement of the yellowness of subcutaneous tissue. This measurement is converted to an estimated bilirubin concentration and displayed in units of mg/dL or μmole/L. This measurement is taken using a dual path optical system. The measurements from each path are then subtracted to minimize the impact of skin

pigmentation. The software in the device then computes the estimated bilirubin concentration based on an established correlation coefficient.

Intended Use:

JM 103 is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn babies and displays a measured value which has been shown to correlate with serum bilirubin. The device is for use in the hospital to assist clinicians in monitoring the status of newborn babies for the development of hyperbilirubinenmia. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements. Newborn infants whose JM 103 test results are indicative of hyperbilitubinemia are evaluated by their doctor(s) for appropriate patient management. Bilirubin levels should be confirmed by other methods (e.g., serum bilirubin) prior to treatment determinations.

Description of Modifications

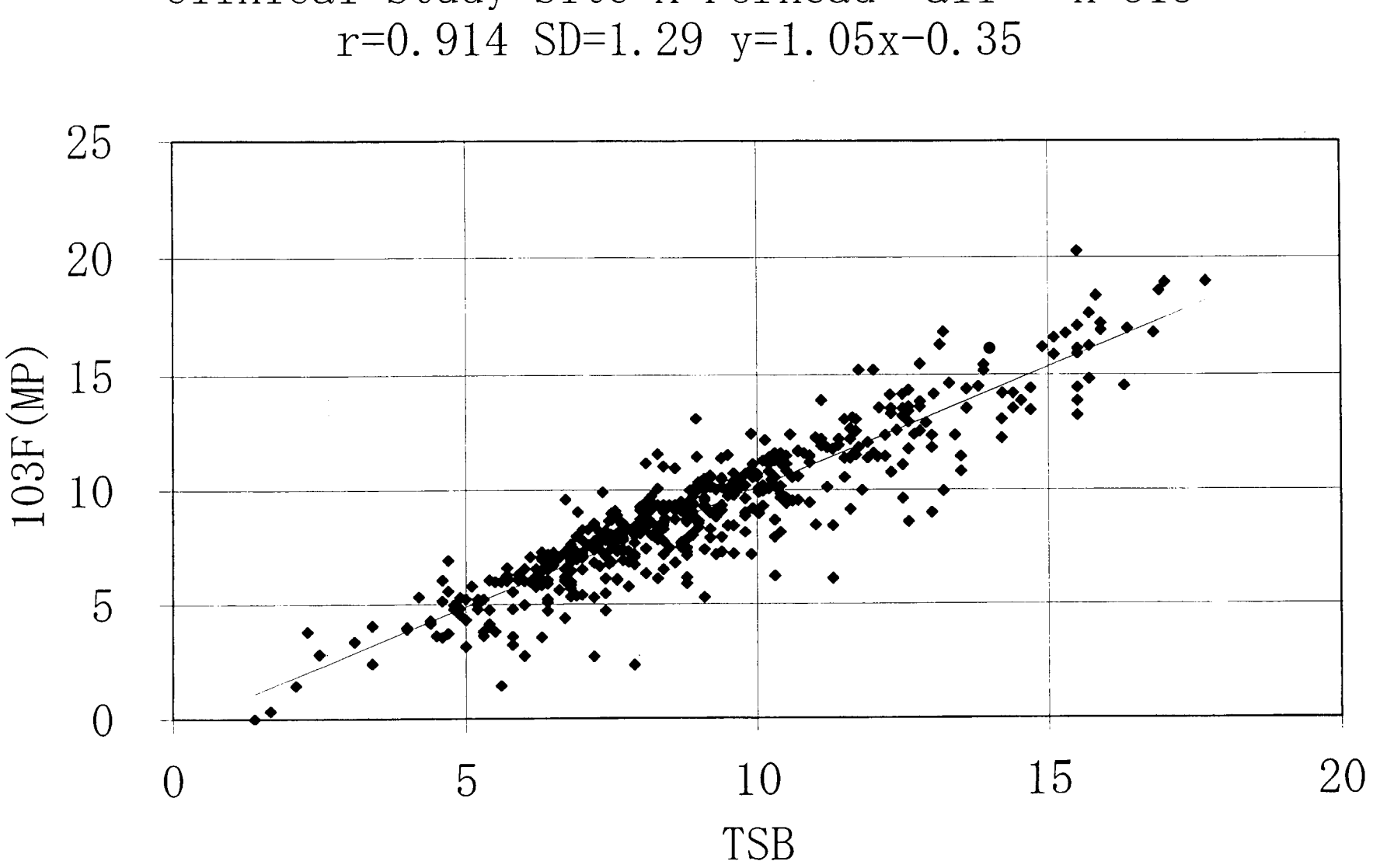
The primary difference between the JM 102 and the JM 103 is that the JM 102 employed a single optical path for measurement and the JM 103 employs a dual optical path.

Performance Assessment

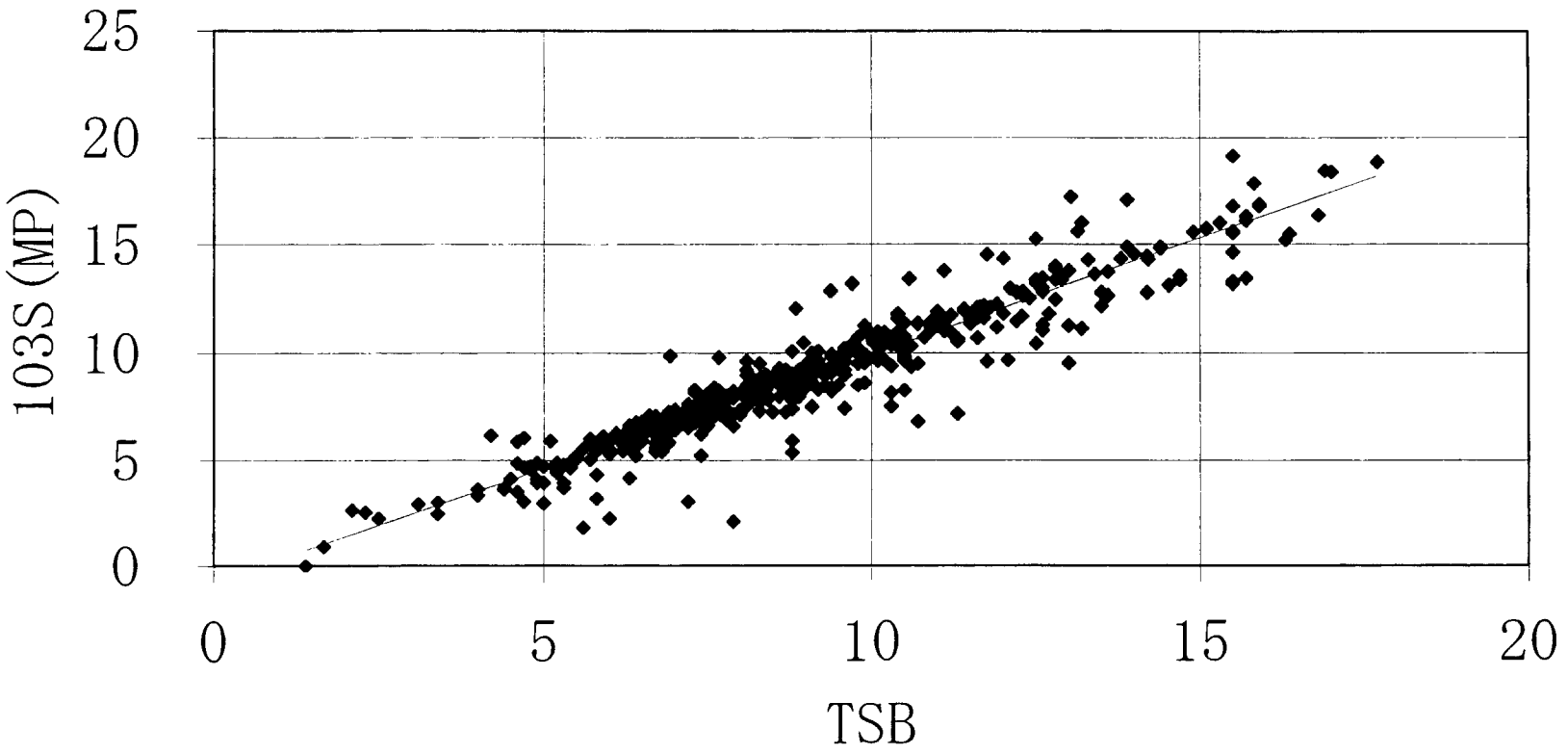
Non-Clinical assessment of this device was performed to ensure that the device operated as intended. In addition, all aspects of the system features and functionality have been bench tested. Software development, validation and verification has been performed.

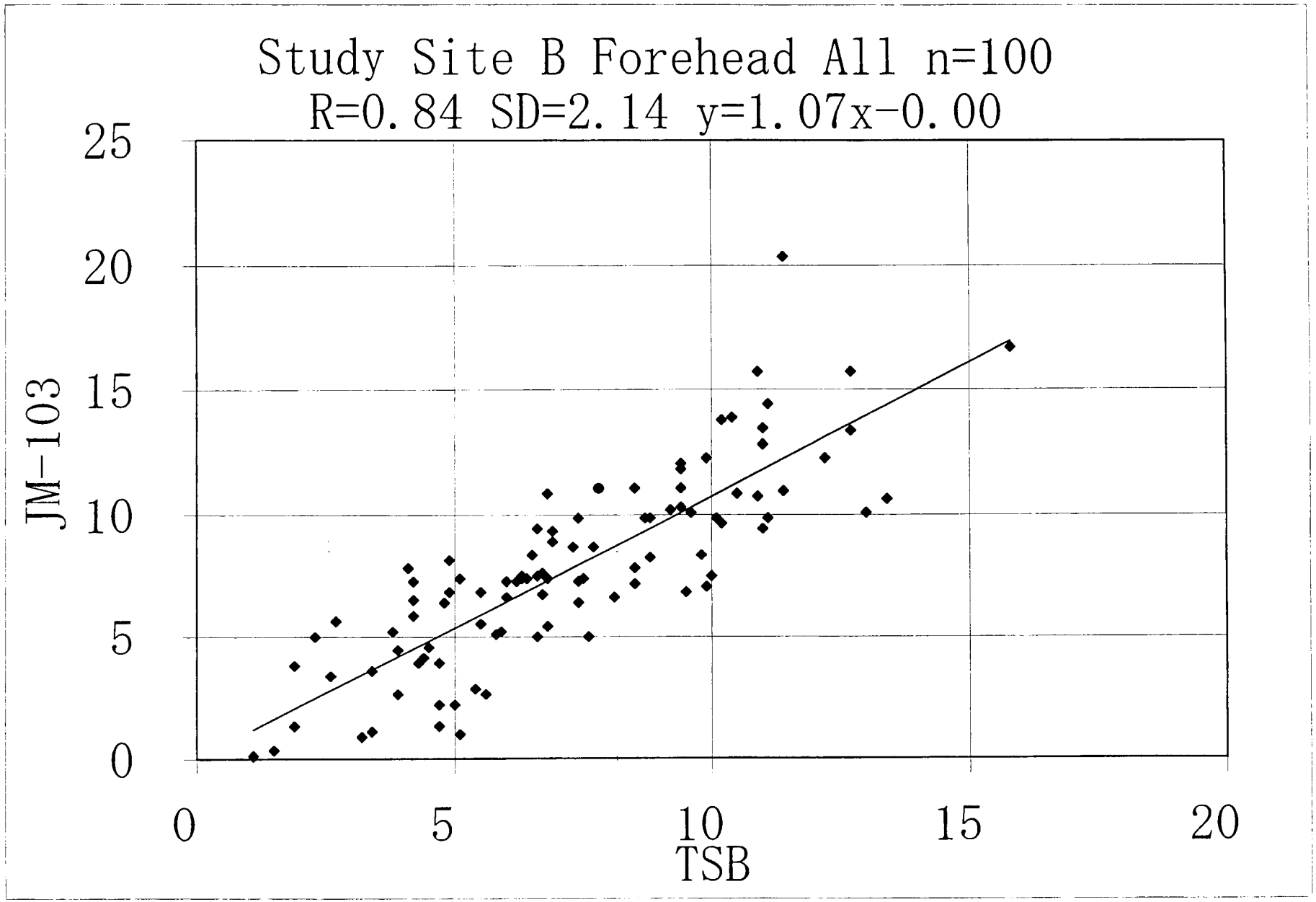
Clinical Assessment of this device was performed at two study sites to establish correlation between the JM 103 estimated bilirubin concentration and total serum bilirubin concentration. The study also demonstrates that the device can be used effectively across diverse populations.

(attach graphs of total population for each site forehead and sternum – 4 charts)


Clinical Study Site A Forhead all n=513
r=0.914 SD=1.29 y=1.05x-0.35
25
20
15
10
5
0
103F(MP)
0
5
10
15
20
TSB

Clinical Study Site A Sternum all n=513
r=0.946 SD=1.02 y=1.07x-0.74




Study Site B Forehead All n=100
R=0.84 SD=2.14 y=1.07x-0.00
JM-103
25
20
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5
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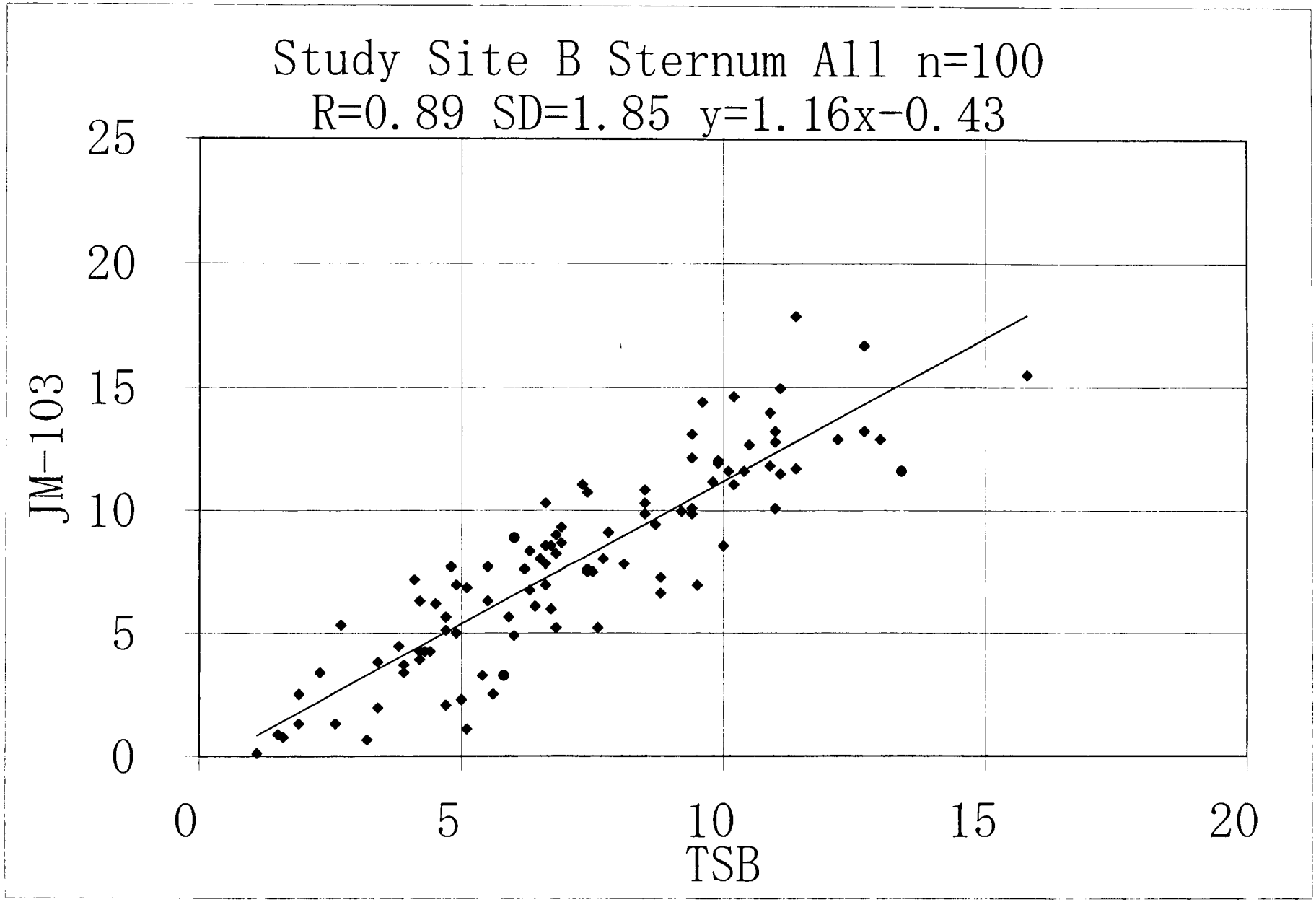
0
5
10
15
20
TSB


Study Site B Sternum All n=100
R=0.89 SD=1.85 y=1.16x-0.43
JM-103
TSB
0
5
10
15
20
25

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Monica Ferrante
Regulatory Affairs
Hill-Rom® Air Shields
330 Jacksonville Road
Hatboro, PA 19040

APR 01 2003

Re: k021622
Trade/Device Name: JM 103 Jaundice Meter
Regulation Number: 21 CFR 862.1113
Regulation Name: Bilirubin (total and unbound) in the neonate test system
Regulatory Class: Class I
Product Code: MQM
Dated: January 10, 2003
Received: January 13, 2003

Dear Ms. Ferrante:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Section A SMDA Requirements

A.1 Indication for Use Statement

510(k) Number: K021622

Device Name: JM 103 Jaundice Meter

Indications for Use:

The Jaundice Meter (JM-103) is a non-invasive transcutaneous bilirubinometer. It measures yellowness of subcutaneous tissue in newborn infants and displays a measured value which has been shown to correlate with serum bilirubin. The device is for use in the hospital to assist clinicians in monitoring the status of newborn infants for the development of hyperbilirubinemia. The device is not intended as a standalone for diagnosis of hyperbilirubinemia. It is to be used in conjunction with other clinical signs and laboratory measurements. Newborn infants whose Jaundice Meter (JM 103) test results are indicative of hyperbilirubinemia are evaluated by their doctor(s) for appropriate patient management. Bilirubin levels should be confirmed by other methods, such as serum bilirubin, prior to treatment determinations.

This device is not intended for home use.

This is a prescription device.

(Please do not write below this line continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K021622

✓ Prescription Use (Per 21 CFR 801.109) OR Over-the-Counter Use